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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,985	10/13/2004	Akihiko Yanaga	2004 1613A	2208

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EXAMINER

FLORY, CHRISTOPHER A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,985	Applicant(s) YANAGA, AKIHIKO	
	Examiner Christopher A. Flory	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/06/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In claim 1, there are several instances in which device components (e.g. a body case, a pair of detecting electrodes) are being claimed in combination with the human body. The human body is not patentable subject matter. To overcome this matter, it is suggested that applicant phrase components as "being adapted to contact a" portion of the body rather than directly claiming them with "*the*" body portion. For example, the fourth clause of claim 1 could be rewritten as --a pair of detecting electrodes located at end portions of said pair of arm portions, respectively, said detecting electrodes *adapted to face a chest portion of a subject--*.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3 and 7-9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Granzotto et al. (US Patent 6,757,392).

Regarding claim 1, Granzotto et al. discloses an electrocardiograph (column 1, lines 60-67) comprising a body case (Fig. 1, headpiece 1) which is held on a chest portion of a subject (ABSTRACT; column 3, lines 8-22); a common electrode provided on a back surface of said body case (Fig. 4, fixed electrode 16); a pair of arm portions which extend from said body case (Fig. 4, arms 18); electrodes for detecting electrocardiographic complex which are provided in both end portions of said pair of said arm portions respectively (Fig. 4, electrodes 17; column 2, lines 1-7); a detecting means for detecting electrocardiographic complex based on signals detected by said electrodes (column 4, lines 51-59); a display means for displaying said electrocardiographic means (Fig. 3, LCD 11 displays the electrocardiographic complex and heart rate); a transmitting means for transmitting said electrocardiographic complex (LCD 11 can be considered a transmitting means; likewise, circuitry or wiring between the disclosed memory and display constitutes a transmitting means); a switching means *capable of* starting detection, display, and transmission of said electrocardiographic complex (Fig. 3, operating keys 13).

Regarding the switching means, Granzotto et al. alternatively discloses switching contacts at pivot joints 19 for the purpose of connecting electrodes 17 to the main body electrode only when the arms are in a fully extended position (column 4, lines 7-27), while the unit will otherwise function as a passive auscultatory device. This can clearly be seen as a disclosure of a switching means that would start detection, display and

transmission of the electrocardiographic complex to the LCD, where data would only be recorded if the device is placed in contact with the chest portion of the subject.

Regarding claim 2, Granzotto et al. discloses a switching means constituted of a pair of push-down switches provided on a front surface of said body case (Figs. 2 and 3, operating keys 13; column 3, lines 24-36). It is noted that the clause "both of said push-down switches are pushed down at once for a specific period" does not distinguish over the prior art because, regardless of the intended button configuration of the Granzotto et al. reference, pressing multiple buttons at once will still activate the unit so long as one is configured to power on the unit. "For a specific period" can comprise any length of time, from a nearly instantaneous button press to holding down one or multiple buttons for any number of seconds, minutes, etc. Therefore, this claim does not distinguish over the Granzotto et al. invention.

Regarding claim 3, Granzotto et al. discloses a switching means constituted of push-down switches which are provided in said electrodes respectively (column 4, lines 1-47).

Regarding claims 7-9, Granzotto et al. shows said body case suspended from a neck of said subject by a suspending means (Fig. 1, flexible bows 31; column 2, lines 3-39).

Claim Rejections - 35 USC § 103

3. Claims 4-6, 10 and 11 stand rejected under 35 U.S.C. 102(b) as anticipated by Granzotto et al. or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granzotto

Art Unit: 3762

et al. in view of Reinhold, Jr. (US Patent 5,339,823, hereinafter referred to as Reinhold'823).

Regarding claims 4-6, it is evident from the scope of the disclosure in Granzotto et al. that non-paste electrodes are inherently necessary for proper function of the Granzotto et al. device. It is well known that stethoscopes operate by being placed temporarily on the chest of a subject and are held there by human force rather than adhesive means. Granzotto et al. further discloses that electrodes 17 are moveable (column 4, lines 1-27) and applied through pressure (column 4, lines 45-47) rather than adhesive means.

Alternatively in the same field of endeavor, Reinhold'823 teaches the use of non-adhesive precordial electrodes on an electrocardiograph device in which human pressure is applied to engage the array of six precordial electrodes with the skin of the chest of the individual in an operative relation (ABSTRACT; column 4, lines 54-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto et al. with the non-adhesive electrodes of Reinhold'823 to provide the Granzotto et al. system with the advantage of temporarily applying the device to a patient in an operative relation with human pressure contact (motivation to combine provided by Reinhold'823 ABSTRACT; column 4, lines 54-66).

Regarding claim 10, Granzotto et al. shows said body case suspended from a neck of said subject by a suspending means (Fig. 1, flexible bows 31; column 2, lines 3-39).

Regarding claim 11, the suspending means of Granzotto et al. is considered to be detachable because the bows 31 are made of a rigidly flexible material known in the art which hold the device on the neck of a user while in their resting configuration, but can be manually separated to allow removal of the device from the neck. The suspending means of Granzotto et al. is detachable to said body case because the bows 31 could be physically removed from the chest-piece 2 without altering in any way the function of the electrocardiograph subsystem.

Alternatively in the same field of endeavor, Reinhold'823 teaches an electrocardiograph device employing a lanyard for engagement around the neck of the user (column 5, lines 1-20). It is well known that a lanyard, such as one used on a set of keys or on a personal camera, comprises a separate flexible loop body (typically fabric) that is attached in a releasable manner to the main body of a device, either by tying through a hole in the device body, attaching to the device body by a key ring, or releasably inserting a male connector portion into a compatible female connector portion. This establishes a detachable quality to the lanyard taught by Reinhold'823. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Granzotto et al. with the detachable lanyard as taught by Reinhold'823 to provide the Granzotto et al. system with the same advantage of releasably engaging the device around a user's neck and allowing for proper vertical adjustment of the electrodes to record an electrocardiographic complex (motivation to combine provided by Reinhold'823, column 5, lines 1-20).

Response to Arguments

4. Applicant's arguments, see page 7, paragraph 3, filed 6 November 2006, with respect to the specification and abstract have been fully considered and are persuasive. The objection to the specification and abstract has been withdrawn.

5. Applicant's arguments, see page 7, paragraph 4, filed 6 November 2006, with respect to the §112 rejection of claims 4-6 have been fully considered and are persuasive. The §112 rejection of claims 4-6 has been withdrawn.

6. Applicant's arguments filed 6 November 2006 have been fully considered but they are not persuasive. Claims 1-3 and 7-9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Granzotto et al. (US Patent 6,757,392).

7. In response to applicant's argument that neither Granzotto nor Reinhold discloses a switching means as recited in claim 1, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Alternatively, Granzotto has been shown to disclose switching contacts on swivel arms 19 in column 4, lines 7-27 that satisfy the argued claim limitation.

8. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

Art Unit: 3762

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Granzotto and Reinhold are directed to devices which collect electrocardiographic data through temporary external application of a medical monitoring device.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

25 April 2007



George Manuel
Primary Examiner